** NOTE: Changes have been made to this document. They are tracked in red.**

Archimedes IndiGO API Usage Document

10/8/12

Background

The ONC, in conjunction with the Million Hearts campaign, is issuing a challenge for an app named Text4Health whose primary goals will be to

- Encourage people who do not know their blood pressure and lipid measurements to be tested so their risk can be accurately estimated
- Inform users of their cardiovascular risk
- Motivate users at high risk to take actions to reduce that risk

Archimedes Inc is developing an API that will calculate users' risk based on their inputs, suggest speciific interventions to reduce their risk and provide quantitative information about the impacts of those interventions on individual risk. The challenge description and formal API specifications are provided in a separate document. The challenge description, which gives an excellent overview of the purpose of the app and how it is intended to respond in the standard use cases, provides overall guidance and intent for the challenge. This document describes the details of how the API will function, including the meaning and interpretation of each of the inputs and outputs, as well as guidance to the app developer on some of the details such as the specific questions to be asked of users when requesting the input information, and the minimum set of output information to be communicated to users in different categories, among other things. This document may be less clear than the challenge descripotion about the intended phases of use for the app because it is intended to cover how the use cases are distinguished and how the API will respond to various non-standard cases (e.g. some biomarkers are entered and others are not…)

Required Inputs

These inputs must be requested by the app and are required to be entered by the user for the API to return a result. Wherever specific questions are listed below, the precise wording of the health information input questions is important to obtaining consistent results and we strongly suggest you follow the exact wording of the questions in quotes above and in the next section. (This is in contrast to the wording of statements about the results covered in subsequent sections in which your creativity is encouraged).

- Age (18-85 allowed)
- Gender (M,F)
- Height (inches)
- Weight (pounds)
- "Do you currently smoke?" (yes, no)

    - Further explanatory text: “Answer yes if you have smoked any cigarettes in the past month”
- “Has a doctor ever told you that you had a heart attack?” (yes, no)
    - Explanatory text “a heart attack is sometimes called a myocardial infarction or MI”
- “Has a doctor ever told you that you had a stroke?” (yes, no)
- “Has a doctor ever told you that you have diabetes?” (yes, no)
        - Explanatory text “Answer yes if you have diabetes mellitus type I or type II”

NOTES FOR DEVELOPERS: We suggest that the app interface be configured so that if the user does not change anything, NO will be returned for the last four questions. For example the interface could have radio buttons that are initially set to “no”. The App should also check for inappropriate values in the above fields and return the appropriate messages to the user (e.g. “you must enter a number between 18 and 85”) if their entries are inappropriate. Appropriate ranges are specified in the API documentation.

Inputs that must be requested but not required to be entered by user

This next section of inputs deals with values (biomarkers) such as blood pressure and cholesterol values that users will likely not to know the first time they use the app. If they do not enter any values, or only enter some values, the IndiGO API will calculate a range for their potential risk and the app will encourage them to obtain testing for the remaining values to enable an accurate estimate of their risk. If the user enters these values, either on the first try or after obtaining testing, then the IndiGO API will calculate their risk and return additional information about options for reducing it.

Suggested wording for question [proposed by Bill Riley]

“Knowing the results of some common medical tests will improve the accuracy of your risk score. If you know these results from your last routine doctor’s visit, enter them below. If you don’t know these results you can leave them blank for now and the program will assist you in getting these tests done.”

The user is then prompted to enter the following values. All are intergers except HbA1c which is continuous, and the acceptable ranges are specified in the API documentation

- Systolic blood pressure
- Diastolic blood pressure
- Total cholesterol
- HDL Cholesterol
- LDL Cholesterol
- HbA1c (IMPORTANT NOTE TO DEVELOPER: this question is *asked only if patient says they have diabetes. HbA1c is typically communicated with one digit after the decimal point. For example 6.9 or 8.2*)

Notes to Developer:

- HbA1c is not a value we expect users to obtain if they do not have it, and it is not one that they should be repeatedly prompted to complete if they have not answered it.
- Explanatory text for blood pressure: "The first number in your blood pressure reading is your systolic blood pressure and the second number is your diastolic blood pressure. For example if your blood pressure is 125/82 (125 over 82) your systolic pressure is 125 and your diastolic pressure is 82.
- Diastolic blood pressure must be less than systolic or an error will be returned
- HDL+LDL must be less than total cholesterol or an error will be returned
- All values have acceptable ranges documented in the API documentation. Values outside these ranges should be rejected by the app with an appropriate message.

Additional optional inputs

The additional questions listed in this section below are entirely optional – that is to say they are not required to be included in the app, however they are useful for calculating more accurate risk estimates and for understanding the personal impact of interventions like additional exercise. Here are several options for how to include them.

Option 1: allow them to be optionally accessed by the user at any point through a link labeled something like "advanced calculation" or "refine your risk estimate".

Option 2: leave them out entirely.

Option 3: the app asks these questions only after the user has successfully filled out the biomarker values. This approach avoids wasting the users time until they have what is needed to obtain a real risk estimate. In this option the app needs to know if the user is done entering the biomarker values listed above in order to decide whether to submit the information to the API (if the information is not complete) or ask the additional questions below (if the information is complete). Since the user can leave some fields blank it may not be obvious when they are done unless a a "continue" or "next" button is built in for the user uses to indicate they are done entering their biomarker values.

Because there are default answers for all the questions below we suggest that it be set up in a way that the user does not have to make any entries unless he/she wants to change the defaults. Here are the questions:

- "Are you currently on any medication to treat high blood pressure?" (yes, no)
  - Further explanation "If you are unsure, then answer no"
  - Default is no
- "How many different medications do you take for your blood pressure?" (1, 2, 3, 4+)
  - *ask this question only if the answer to the above question was yes.*
  - Default is one.
- "Are you currently on medication to lower your cholesterol?" (yes, no)

    - Default to no
- Do you take aspirin daily for your heart? (yes NO)
    - Further explanation "answer yes if you take either full strength or junior aspirin daily"
    - Default to no
- "How many hours do you spend doing moderate physical activities such as brisk walking in a typical week" (hrs per week) (0 - 59)
    - Further explanation: "Moderate physical activities are ones that cause a slight elevation in heart rate or breathing such as raking leaves, mowing the lawn, or heavy cleaning"
    - Default to zero
- "How many hours do you spend doing vigorous physical activities such as running in a typical week" (hrs per week) (0 - 29)
    - Further explanation: "Vigorous physical activities are ones that cause heavy sweating or large increases in breathing or heart rate for at least 10 minutes at a time. Some examples are running, lap swimming, aerobics classes or fast bicycling"
    - Default to zero
- "Have any of your first-degree relatives (parent, full-blooded brother or sister, or child) had a heart attack before the age of 55?" (yes, no)
    - Further explanation "A heart attack is also called a myocardial infarction or MI"
    - Default to no

Outputs returned when biomarkers are not entered ("Get Tested" Phase)

All five critical biomarkers (systolic, diastolic, total cholesterol, LDL, HDL) must be entered to move to risk calculation phase. This section deals with the output of the API if none or only some of them are entered. In that case, the outputs detail the upper and lower ends of a range of possible risk and the patient will be encouraged to obtain screening. The upper and lower bounds define a range that includes the risks of most people who match the information they input.

Technical Note: IndiGO calculates the range of risk by sampling the missing values multiple times from a posterior probability distribution modeled on the NHANES database (a sample of the US population) and consistent with (conditioned on) the variables that were input. This process, called multiple statistical imputation, generates the distribution of risk values that might be expected for the person with any particular set of known values. The upper and lower bounds on the risk returned by the API are calculated by looking at certain cut-points in this distribution of possible risk values (e.g. the 5^{th} and 95^{th} percentile).

The specific API outputs for the range of risk are listed below.

UPPER bound of CVD Risk

- Percent Risk (5-yr) (continuous number between 0 and 100).
- Percentile of risk within population of same age and gender (1-99 integer). 99th percentile is the one corresponding to highest risk

- Ratio to healthy for age (continuous number between 0 and 1000)
- Rating for age (integer between 1 and 5, where 5 is the highest risk). You can think of these ratings as low (good), medium, high, very high, extremely high
- Absolute Rating (integer between 1 and 5, where 5 is the highest risk). You can think of these ratings as acceptable, moderately high, high, very high, extremely high)

LOWER bound of CVD Risk

- Returns same values as listed for UPPER bound

Recommendation

- Suggest you go to a pharmacy for further screening tests (0, 1, 2, or 3)

How the app communicates the meaning of the upper and lower bounds to the user is for the most part up to the developer. For example the developer could communicate only about the upper bound using the category information by age "your risk could be (low, medium, high…using the rating of the uupper bound) for your age …" or it could give information on both the upper and lower bounds. For example "your risk is likely to be between _ and __" or "Most people who match the information you have given us have risks between __ and __"…. Alternatively it could communicate about risk by percentile or absolute risk. The reason for communicating the risk information in multiple formats is to give options to the developer and it is not intended that all this information be communicated to the user. The developer is expected to use their skills and creativity along with the most useful information in a way that will be most effectively motivate users to obtain screening. There is however a minimum set of information that we feel should be communicated for the tool to be effective, and that information varies depending on the user. Specifically

- If the upper absolute risk rating is >=3 then that rating should be communicated (in some manner)
- The upper ratio to healthy risk for age should always be communicated except in the case where the upper absolute risk rating is >=3 and the ratio < 2 in which case it is not necessary to communicate the ratio. (For example if the user's upper absolute risk is level 4 and his upper risk ratio is only 1.5 it is only necessary to communicate the upper absolute risk rating)

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It is fine to provide additional information to the minimum set specified below, or not, or to make it available as an option for to those who select to view it.

Table of cases and examples: The table below shows the minimum information to communicate in table format. The example wording in the table illustrating communication of the minimum information is NOT intended as a template or "recommended" wording.

CASE	Example	Minimum Information to	An example communication of	An example Communication of

		Communicate	minimum information	more than minimum information
Upper absolute risk rating >=3, upper ratio < 2	Upper abs risk rating 5 and upper ratio =1.3	Upper absolute Risk Rating	While we don't have all the information needed to calculate your risk, based on what you have told us it could be extremely high. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.	While we don't have all the information needed to calculate your risk, based on what you have told us it could be extremely high. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.
Upper absolute risk rating >=3, upper ratio >=2	Upper abs risk rating 4 and upper ratio 3.1	Upper absolute risk rating and upper ratio to healthy risk for age	While we don't have all the information needed to calculate your risk, based on what you have told us it could be very high. It could be as high as 3.1 times what is considered healthy for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.	Your risk could be high. Depending on your blood pressure and cholesterol It could be anywhere from 0.4 to 3.1 times what is considered healthy for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.
Upper absolute risk rating <3, upper ratio >= 2	Upper absolute risk rating 2, upper ratio 2.5	Upper ratio to healthy risk for age	We don't have all the information needed to calculate your risk, but based on what you have told us it could be as high as	Depending on your blood pressure and cholesterol your risk could be anywhere from 0.3 to 2.5 times what is considered healthy

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			2.5 times what is considered healthy for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.	for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.
Upper absolute risk rating <3, upper ratio < 2	Upper absolute risk rating 2, upper ratio 1.2 Lower ratio 0.3	Upper ratio to healthy risk for age (different communication recommended)	Depending on your blood pressure and cholesterol your risk could be higher than what is considered healthy for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.	Depending on your blood pressure and cholesterol your risk could range from 0.3 to 1.2 times what is considered healthy for your age. It is important for you to check your blood pressure and cholesterol to understand your risk better and learn what you can do about it.

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Here is an alternative wording for the reason to obtain testing (proposed by Audie): "to get a more accurate or fuller picture of your heart health, it is important to have your blood pressure and cholesterol checked. Estimates we have for your heart health are less accurate without these screening tests."

The ratio, percent risk and percentile fields should be communicated quantitatively (whether as a number, visually, or graphically) to be meaningful. The risk categories are not quantitative and can be communicated in any manner that is effective: text (e.g. low, moderate, elevated, high, very high, or e.g. Excellent, good, elevated, high, very high, extremely high) is only one option.

Communicating Screening Recommendation:

The output contains a field that communicates four levels of recommendation for additional biomarker screening. While the way in which this is communicated to the user is entirely up to the developer, the

levels may be useful in calibrating the appropriate level of urgency to be used in the communication. The levels can be conceptualized as follows:

Level 0: No screening is needed as all the biomarker information was entered

Level 1: Screening would be useful. The user is likely in a lower risk category. The app might communicate that it is important to know your blood pressure and cholesterol to understand your risk better and to keep track of it over time.

Level 2: Screening is important. The user could be at high risk or very high risk for age. It is important he get screened to understand their risk and take action if it is high

Level 3: Screening is urgent. The user is likely to be at very high risk and treatment could be critical.

Outputs returned once biomarkers are specified (Risk Calculation Phase)

If all five biomarkers are entered, and additional questions are answered, then the outputs listed below are returned. Note that these are actual risk estimates (not upper or lower bounds ends of a likely range as in the previous section). The sub-bullets bellow show the meaning of the variable by giving an example sentence in which it could be used.

CVD risk

- Percent Risk (5-yr) (continuous number between 0 and 100)
  - Your risk of having a heart attack or a stroke in the next five years is _ %
- Percentile of risk within population of same age and gender (1-99 integer). 99th percentile is the one corresponding to highest risk
  - Your risk of having a heart attack or a stroke is in the _ percentile for your age
- Ratio to healthy for age (continuous number between 0 and 1000)
  - Your risk of having a heart attack or a stroke is __ times as high as what is considered a healthy risk level for your age
- Rating for age (integer between 1 and 5, where 5 is the highest risk)
  - Your risk of having a heart attack or a stroke is (low, medium, high, very high, extremely high) for your age
- Absolute Rating (integer between 1 and 5, where 5 is the highest risk)
  - Your risk of having a heart attack or a stroke is (good, moderately high, high, very high, extremely high)

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Minimum risk information to communicate after risk is calculated:

The reason for communicating the risk information in the multiple formats listed above is to give options to the developer and it is not intended that all this information would necessarily be communicated or

even available to the user. Generally the developer is expected to use their skills and creativity to choose the most effective subset and communicate it in a way that will be most effective in motivating users who are at high risk to see adhere to their existing medications, see a doctor, and/or make lifestyle changes. We have included below some guidelines about the minimum information that should be communicated for this to be effective. Specifically

If the absolute risk rating is >=2, then that rating should be communicated (in some manner)

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The ratio to healthy risk for age should always be communicated except in the case where the absolute risk rating is >=2 and the ratio < 2 in which case it is not necessary to communicate the risk for age. (For example if the user's absolute risk is level 3 and his risk ratio is only 1.5 it is only necessary to communicate the absolute risk rating)

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As before, it is fine to provide additional information to all users, to make it available as an option to those who select it, or not to use it at all.

Table of examples: Note that wording is for example purposes only and is not intended as a suggested wording

CASE	Example	Minimum Information	An example communication of minimum information
absolute risk rating >=2, ratio < 2	abs risk rating 4 and ratio =1.3	absolute Risk Rating	Your risk is very high.
absolute risk rating >=2 ratio >=2	abs risk rating 2 and ratio 3.1	absolute risk rating and ratio to healthy risk for age	Your risk is moderately high and t is 3.1 times what is considered healthy for your age.
absolute risk rating <2 ratio >= 1	absolute risk rating 1, ratio 2.5	ratio to healthy risk for age	Your risk is 2.5 times what is considered healthy for your age.
absolute risk rating <2, ratio <=1	absolute risk rating 1, ratio 0.8	ratio to healthy risk for age	Good job. Your risk is considered healthy. Keep doing what you are doing.

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The ratio, percent risk and percentile fields should be communicated in a quantitative fashion (whether as a number, visually, or graphically) to be meaningful. The risk categories can be communicated in any manner that is effective -- text (e.g. low, moderate, elevated, high, very high, or e.g. excellent, good, elevated, high, very high, extremely high) is only one option.

Intervention Outputs:

The outputs below inform the patient about things they may do to reduce their risk, and how much each might be expected to reduce their risk. These are personalized calculations insofar as they depend on the patient's personal data. For example the percent reduction in risk resulting from exercise is different for each individual depending on their current blood pressure,, cholesterol medications, current exercise etc. The language in quotes is NOT intended as a template for app developers to use, but is included in this document to clarify the meaning of the result being returned. Note that these output fields can be blank if the intervention is not recommended. This could happen for a number of reasons including that the patient is not eligible (e.g. your BMI must be >= 25 to be eligible for weight loss) or the benefit is too low to be worth mentioning. (e.g. a 5% risk reduction), or other reasons.

- Percent by which taking your medications reduces your risk ("stop meds")
  - E.g. "It is important to be consistent about the medications you are currently taking to reduce your blood pressure or cholesterol. Based on the information you have entered, your current medications (including aspirin if you take it) reduce your risk by about __% from what it would be if you were not taking them."
- Percent reduction in risk possible with medication
  - "A doctor may be able to reduce your risk by __% by managing your blood pressure and cholesterol"
- Percent reduction in risk possible with additional 3hrs/wk of moderate exercise
  - "Adding three hours of moderate exercise such as brisk walking to your weekly routine will reduce your risk by __%."
- Percent reduction in risk possible with additional 3hrs/wk of vigorous exercise
  - "Adding six hours of moderate exercise or three hours of vigorous exercise such as runnig to your weekly routine will reduce your risk by __%. Discuss with a doctor before starting any exercise program."
- Percent reduction in risk possible with weight loss
  - "If you lose 5% of your body weight and do not regain it, you will reduce your risk by __%"
- Number of pounds of weight loss required (5% of current weight)
  - This enables the app to weight loss in pounds instead of the percent weight loss e.g. "if you lose 11 pounds and do not regain it…"
- Percent reduction possible with smoking cessation
  - "If you quit smoking you will reduce your risk by __%"
- Pct reduction possible with all interventions
  - "If you do all of the above you could reduce your risk by __%"
- Categorical risk relative to age possible with all interventions
  - "If you do all of the above your risk would be (low, medium…_) for your age"

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Doctor recommendation levels

Doctor recommendation levels indicate urgency the user see a doctor. Factors that in combination will trigger an urgent recommendation are high risk, high risk for age, the fraction by which that risk can be controlled by reduced by treatment of blood pressure and cholesterol, and whether the patient is not

taking any medications (indicating they are not under the care of a physician). The messaging is up to the developer, but the following should give a sense of what we are trying to communicate,

- Output =0: It is not necessary to recommend the user discuss with a doctor
- Output =1: standard messaging along the lines of "you should discuss your heart risk and steps you can take to reduce it with your doctor"
- Output = 2: This code indicates an escalated importance of discussing with a doctor. A message could be something like "You should see a doctor to discuss your heart risk" or "it is important that you discuss your heart risk with your doctor"
- Output – 3: This code indicates that discussing with a doctor is very high importance and the message could be something like "It is very important that you see a doctor soon to discuss things you can do to reduce your risk"

Warnings

This field currently communicates warnings that the input data does not look quite right. It may also be used later to notify the app about other special cases that require messaging to the user. While there are data input ranges to filter out input values that are not possible, the warnings conveyed in this field deal with data that falls within those ranges but does not look right in combination. (For example a blood pressure of 100/98) Warning codes are returned so the app can inform the user of entries that seems suspect although they were accepted and used to generate a result. Here is the list of codes along with suggested messages to the user

- 1: "The values you entered for your blood pressure entries are unusual and may not be correct. We suggest you check your entries and if you get this message again have your blood pressure re-tested."
- 2: "Your cholesterol values (Total, LDL, HDL) you entered are unusual and may not be correct. We suggest you check your entries and if you get this message again have them re-tested"
- 3: "The blood pressure and cholesterol values you entered are unusual and may not be correct. We suggest you check your entries and if you get this message again have them re-tested"

Outputs that may be returned in either phase

These API outputs relate to the biomarker entries such as blood pressure and LDL cholesterol and typically we would expect to see them after all the biomarkers are entered when the risk is returned, however it is possible that a user enters an incomplete set of biomarkers and in this case it would still be important to inform them if any of their entries are values requiring treatment despite the fact that the app may not be able to return a risk at this point. This is an additional message to the messages about risk, but it might make sense to couple it with the information about how much a doctor might be able to reduce their risk by managing their blood pressure and cholesterol since the two are linked. Here are the outputs:

- Elevated blood pressure (yes no)
    - Suggested message to user: “You may have elevated blood pressure. You should consult with your doctor or primary care provider about things you can do to control it”
    - can be returned so long as systolic blood pressure is entered by user
    - logic based on standard national guideline (JNC7 or JNC8)
- Elevated cholesterol (yes no)
    - Suggested message to user: “Your cholesterol levels exceed national standards and are contributing to your risk. You should consult with your physician about things you can do to improve your cholesterol levels”
    - can be returned if any of TC, LDL or TG are entered
    - logic will be based on standard national guideline (ATP)

ADDITIONAL NOTES

The definition of cardiovascular risk used in this application is the 5-year risk of an MI or Stroke. It does not include Transient Ischemic events (called TIAs), angina, or other outcomes and diagnoses sometimes included in risk estimates.

The thresholds for the various risk rating levels that are returned for risk) relative to age or absolute risk have not been determined at the time of writing this document, but should not impact app development

The exact definition of the upper and lower bounds on risk referred to above has not yet been determined definitively but will be calculated by looking at the distribution of possible risk values that could be obtained depending on how the missing information is filled in. A likely definition is the 5^{th} and 95^{th} percentile of the distribution.

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